IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant: Jacobus M. Lemmens et al.

Title: ***Paroxetine Compositions and Processes for Making the Same***

Appl. No.: 10/678,082

Filing Date: 10/6/2003

Examiner: Chris E. SIMMONS

Art Unit: 1612

Confirmation Number: 4414

APPELLANT'S REPLY BRIEF UNDER 37 C.F.R. § 41.41

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Sir:

Under the provisions of 37 C.F.R. § 41.41 and in response to the Examiner's Answer that was mailed on June 23, 2011 ("Answer"), Appellants submit this Reply Brief. The filing due date for filing this response is August 23, 2011, and so this brief is timely filed.

Appellants believe that no fee is necessary in connection with this brief. However, the Commissioner is hereby authorized to charge any fees and credit any overpayment to Deposit Account No. 19-0741.

ARGUMENT

The Examiner's Answer mailed on June 23, 2011 compounds factual error that should compel reversal of the Examiner's rejection of appealed claims 51 – 59 under 35 U.S.C. § 103(a) in view of Pathak, Benneker, and Chu. The present Reply Brief unravels the error.

I. Chu Teaches Two Methods of Manufacture of Anyhydrous Calcium Hydrogen Phosphate (CHP) That Do Not Hint at pH of CHP

The central error underlying the rejection is the Examiner's assertion that Chu attributes certain pH to CHP – allegedly this is the same pH as recited in the appealed claims – that is produced by a method of Chu. The error is a misidentification of the substance to which Chu attributes a value for pH. As explained in detail below, Chu teaches two different methods of making anhydrous CHP, and neither of these methods so much as hint at the pH of the produced anhydrous CHP.

First, as the Examiner appreciated, Chu recounts known methods of producing anhydrous CHP. These include (1) precipitation from a slurry of lime and phosphoric acid,[1] (2) boiling a slurry of calcium phosphate dehydrate at low pH drive off water,[2] (3) precipitation from a mother liquor,[3] and (4) preparation from a solution in a mill.[4]

Second, Chu proposed that an inventive anhydrous CHP can be prepared by "dehydrating dicalcium phosphate dehydrate powder."[5] To accomplish the dehydration, Chu disclosed **(A) thermal dehydration**, which entails heating the dehydrate.[6] Chu stated that anhydrous CHP

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[1] Chu, col. 1, lines 51-63.

[2] Chu, col. 1, line 63 to col. 2, line 16.

[3] Chu, col. 2, lines 17-20.

[4] Chu, col. 2, lines 20-23.

[5] Chu, col. 2, lines 45- 48.

[6] Chu, col. 2, lines 51-55.

"can also be prepared" by **(B) boiling the dehydrate** at "pH's ranging from neutral to about 3".[7] Chu's Example 1, which the Examiner cites a number times, demonstrates method (A).

A fundamental error is the Examiner's collapsing Chu's methods (A) and (B) into just one, despite Chu's clear delineation between two different methods, (A) and (B), of making anhydrous CHP. No clearer example of this error is the Answer's characterization of "dicalcium phosphate dehydrate . . . which is **boiled (i.e., heated in a drier as outlined in working example 1** at column 6, lines 8-13) to yield the formation of anhydrous CHP and a drop in the pH by 1 to 2 units."[8] The emphasized portion of the quoted passage, particularly use of the abbreviation "i.e.",[9] simply conflates (A) boiling and (B) heating in a drier. Yet, not even Chu admits of this distortion: common sense of the skilled person says that boiling occurs in a liquid, such as water, and heating a solid in a drier does not involve boiling a liquid.

Chu's description of thermal dehydration (B) as described above hints at absolutely nothing about pH of the produced anhydrous CHP. In this context, Appellants have repeatedly insisted throughout prosecution and in the present appeal that Chu's only disclosure of pH relates to Chu's method (A), concerning the boiling of the CHP dehydrate. Specifically, Chu stated that "[b]oiling can be conducted at pH's ranging from neutral to about 3."[10] A skilled artisan would understand that the term "boiling" refers to a liquid, but not just any liquid. That is to say, only an aqueous solution can have a pH, by definition, as any chemist would know. Hence, the skilled artisan would plainly understand Chu's boiling method to entail the boiling of CHP dihydrate in an aqueous solution that, according to Chu, has been adjusted to pH neutral to about 3.

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[7] Chu, col. 3, lines 42-44.

[8] Answer, page 8 (emphasis added).

[9] Appellants understand the Examiner's correct usage of "i.e.", an abbreviation for the Latin phrase *id est*, literally "that is."

[10] Chu, col. 3, lines 44 – 45.

Also according to Chu, dehydration by the boiling method will "cause a drop in pH of from about 1 to pH units."[11] Common sense and a scientific grasp of pH say that the drop in pH refers to the aqueous media in which the CHP dehydrate is boiled. Yet, the Answer repeatedly alludes to a general notion that heating CHP dehydrate as taught by Chu results in a pH drop of *CHP*.[12]

This is not at all what Chu teaches: the skilled reader of Chu would understand that boiling the CHP dehydrate causes a pH drop of the medium, *i.e.*, an aqueous solution, in which CHP is boiled. Again, there is no sense whatsoever in referring to pH of a solid, but only pH of an aqueous solution. Entirely consistent with this correct interpretation of Chu is the reference's further teaching that one can neutralize the pH "after anhydrous formation" by adding a base."[13] The skilled artisan knows that one does not add a base to neutralize pH of a solid; rather, one adds a base to an aqueous solution to neutralize acid in the solution.

Thus, whilst Chu provides ample guidance for adjusting pH for boiling CHP dihydrate, Chu does not hint at any pH for the thermal (oven) dehydration of the dehydrate because pH of a solid in an oven simply makes no sense. For the sake of absolute clarity in this context, Appellants point out that the pH recited in the appealed claims is not pH of a solid, but rather the "pH . . . determined by forming a slurry of the solid composition with water and measuring the pH of the slurry, as is understood by worked skilled in the art regarding the pH of a solid composition."[14] From the preceding discussion, it should be manifestly clear that Chu does not refer to pH in this context. That is to say, Chu's disclosure of pH refers to pH adjustment of the medium in which CHP is boiled, not to pH of water in which the solid CHP, once made, is then slurried.

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[11] Chu, col. 3, lines 45-46.

[12] Answer at page 8 ("[t]his dehydration process used to form CHP anhydrous leads to a drop in the pH"); ("it is clear that CHP dehydrate is heated . . . and is converted to anhydrous CHP and apparently drops the resulting pH by 1 to 2 units as well.").

[13] Chu, col. 3, lines 46 – 47.

[14] Specification, page 7 lines 22 - 24

More forcefully asserting a characterization of Chu, the Examiner argued a two-fold proposition. First, Chu allegedly teaches neutralization of pH "of CHP anhydrous compound" that is "an even clearer teaching of a pH for CHP anhydrous that is 7."[15] Second, the Examiner relied upon teaching in Appellants' specification, concerning use of non-alkaline CHP, such as that allegedly taught by Chu, to achieve the "desired pH."[16] From these points the Examiner reasoned that a skilled person could reasonably expect Chu's anhydrous CHP to impart a similar pH to a composition into which the CHP is incorporated.[17]

Fatal error in the line of reasoning above arises from the fact that Chu does not teach neutralization of anhydrous CHP. What Chu actually states, and what the Examiner quoted faithfully in the Answer,[18] is that a pH drop occurring during dehydration in Chu's boiling method can be neutralized by addition of a base.[19] Hence, the error, as discussed more fully above, is the Examiner's attribution of pH to *anhydrous CHP*, whereas Chu, in contrast, teaches the only scientifically plausible explanation: addition of base neutralizes pH of the *water solution* in which anhydrous CHP is boiled as a slurry and thereby produced. Therefore, Chu does not hint at any pH of the produced anhydrous CHP, and it follows that the skilled person cannot reasonably expect what pH might result by incorporating into it Chu's anhydrous CHP.

II. The Skilled Person Was Not Motivated to Thermally Dehydrate "Di-Tab" so as to Produce "A-Tab"

The Examiner committed further error in theorizing that a skilled person would have been motivated to thermally dehydrate Pathak's Di-Tab, a dehydrate of CHP.[20] According to the

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[15] Answer, page 10.

[16] Answer, page 10.

[17] *See* Answer, pages 10-11.

[18] Answer, page 8.

[19] Chu, col. 3, lines 42-48.

[20] Answer, page 11.

Examiner, carrying out a dehydration on Di-Tab in a manner taught by Chu would produce A-Tab, which is anhydrous CHP, so as to improve compressibility and to "attain the desired pH."[21]

Even a casual reading of Chu, however, debunks this theory, for Chu is concerned with an improvement of a new anhydrous CHP over known *anhydrous CHP*. Specifically, Chu states that known anhydrous CHP "alone cannot be used in dry direct compression as the particles are too fine and will not flow into the compression dies."[22] Chu's solution to this problem is a "new soft agglomerated anhydrous dicalcium phosphate which can be direct compression tableted . . ."[23] Thus, Chu does not suggest an improvement to CHP dihydrate *via* dehydration, as the Examiner supposed, but rather teaches new anhydrous CHP as a solution to known anhydrous CHP.

In fact, Chu states nothing about tableting compositions that comprise CHP dehydrate. Therefore, the reader of Chu would not have perceived any compressibility problem with tableting compositions containing CHP dehydrate and, accordingly, the person would have no reason to dehydrate it.

Pathak, too, fails to support the Examiner's theory. In particular, Pathak's exemplary compositions contain Di-Tab and tablets of the same "are made satisfactorily on a single punch or a Rotary press."[24] In view of Pathak's disclosure, as with Chu's, a skilled person would have no reason to replace Di-Tab with an anhydrous form of CHP. Therefore, in contrast to the Examiner's assertion, Chu and Pathak would not have motivated the person to modify Pathak compositions by dehydrating Di-Tab in a manner taught by Chu.

The Examiner erred also by stating without a scintilla of factual support that "[d]ehydrating 'Emcompress' or 'Di-Tab' results in 'A-Tab,' the same product preferred by

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[21] Answer, page 11.

[22] Chu, col. 2, lines 24-26.

[23] Chu, col. 2, lines 36-37.

[24] Pathak, col. 3, lines 36-37.

applicant."[25] Whence does this knowledge derive? The onus is first upon the Examiner to provide a "sound basis for believing that the products of the applicant and the prior art are the same . . ."[26] Only then would burden shift to an applicant to show that they are not.[27] Yet here, the Examiner's only basis is a fact-starved assertion that does not rise to the level of "sound basis." There is no disclosure or hint whatsoever in the cited prior art that dehydration of Pathek's Di-Tab gives A-Tab, much less any anhydrous CHP that, when combined in a composition as claimed, results in a composition having pH 5.0 to 6.0.

III. Because the Cited Prior Art Does Not Suggest Every Claimed Element, the Claimed pH of 5.0 to 6.0 is not an Inherent Feature of the Prior Art

The Examiner's elaboration on a theory of inherency exacerbates factual error discussed above by asserting that an allegedly obvious combination of components inherently gives rise to the claimed pH range of 5.0 to 6.0.[28] Critically, the Examiner stressed in this context that Chu suggests A-Tab as resulting from dehydration of CHP.

Yet, as the discussion above plainly reveals, neither Chu nor any other evidence of record remotely hints that A-Tab is a product of the dehydration process taught by Chu. Chu moreover does not teach or suggest a pH of any anhydrous CHP. Therefore, the cited prior art does not, in fact, suggest "every ingredient in the claim compositions."[29] Accordingly, the Examiner's purported combination of prior art "ingredients" is not fixed and, hence, there is no fixed combination to which an inherent property can possibly attach.

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[25] Answer, page 6.

[26] *In re Spada*, 911 F.2d 705, 708 (Fed.Cir. 1990).

[27] *Id.*

[28] *See* Answer, page 12.

[29] Answer, page 12.

IV. Conclusion

The obviousness rejection should be reversed because it embodies factual error. In summary, Chu does not disclose or hint at pH of any CHP product. Whilst the reference teaches two distinct methods for the manufacture of anhydrous CHP, dry oven heating and boiling, respectively, only the boiling method implicates pH, and then only as a property of the aqueous solution in which CHP dehydrate is initially slurried. The Examiner asserted that Chu's oven heating method converts Pathak's CHP dehydrate, Di-Tab, into anhydrous CHP, A-Tab, for obvious use in Appellants' claims, but no basis, reasonable or otherwise, was offered to support this bare assertion. Chu and Pathak moreover fail to engender any motivation for even attempting the alleged conversion. In no event do these possibilities hint at anhydrous CHP that, when combined with the presently recited components, give rise to a composition exhibiting a pH of 5.0 to 6.0.

For at least these reasons, Appellants respectfully urge the Board to reverse the rejection.

Respectfully submitted,

By 

Date August 10, 2011

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